Electronically filed

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 7,645,733 B2

Issued: January 12, 2010

Patentee: Brines *et al.*

For: TISSUE PROTECTIVE CYTOKINES FOR THE TREATMENT AND PREVENTION OF SEPSIS AND THE FORMATION OF ADHESIONS

Application No. 10/573,905

International Filing Date: September 29, 2004

Attorney Docket No. 10165-042-999

REQUEST FOR CERTIFICATE OF CORRECTION

Commissioner for Patents
ATTN: Certificate of Correction Branch
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.322, the Patentee hereby requests the issuance of a Certificate of Correction in connection with the above-identified patent. A Certificate of Correction setting forth the necessary correction is submitted herewith.

On the title page of the issued patent, the city of co-Assignee Warren Pharmaceuticals, Inc. is incorrectly recited as "Ossinin." Patentee requests that the city of co-Assignee Warren Pharmaceuticals, Inc. be amended to recite "Ossining."

Claim 3 in the issued patent incorrectly recites " . . . method of **claims** 1, wherein the carbamylation of the **erythropeietin on** at least six lysine . . . ." Patentee requests that claim 3 be amended to recite " . . . method of claim 1, wherein the carbamylation of the erythropoietin is on at least six lysine . . . ."

In support of its request, Patentee submits herewith as Appendix A copies of the following documents in connection with U.S. Application Serial No. 10/573,905, on which the above-identified patent is based: Notice of Recordation Document, dated July 13, 2006; Fee Transmittal mailed with payment of the issue fee on November 20, 2009; and an Amendment,

filed April 24, 2009, which contains a listing of the claims that were allowed pursuant to the Notice of Allowability mailed August 21, 2009 (also included in Appendix A).

Patentee respectfully submits that no fee is required for this Request because the error was incurred through error of the Patent Office. However, if any fee is deemed necessary, please charge such fee to Jones Day Deposit Account No. 50-3013.

by: Sebastian Kurhiec
Reg. No. 52,413

Respectfully submitted,

Date: May 19, 2010

Laura A. Coruzzi 30,742

Laura A. Coruzzi (Reg. No.)

JONES DAY
222 East 41st Street
New York, NY 10017
(212) 901-9028

Enclosures

PRINTER'S TRIM LINE

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO.	:	7,645,733 B2
DATED	:	January 12, 2010
INVENTOR(S)	:	Michael Brines Anthony Cerami Thomas Coleman Osman Yilmaz

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, under item (73) Assignees, replace "**The Kenneth S. Warren Institute, Inc.**, Ossining, NY (US); **Warren Pharmaceuticals, Inc.**, Ossinin, NY (US)" with -- **The Kenneth S. Warren Institute, Inc.**, Ossining, NY (US); Warren Pharmaceuticals, Inc., Ossining, NY (US) --.

Claim 3, at column 28, lines 25-28, replace "method of claims 1, wherein the carbamylation of the erythropeietin on at least six lysine" with -- method of claim 1, wherein the carbamylation of the erythropoietin is on at least six lysine --.

MAILING ADDRESS OF SENDER:
JONES DAY
222 East 41st Street
New York, New York 10017-6702
(212) 326-3939
NYI-4276920v1
FORM PTO 1050

PATENT NO. 7,645,733 B2

No. of add'l. copies
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

JULY 13, 2006

PTAS

103249113A

FREDERICK J. HAMBLE
WARREN PHARMACEUTICALS, INC.
712 KITCHAWAN ROAD
OSSINING, NY 10562

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 571-272-3350. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, MAIL STOP: ASSIGNMENT SERVICES BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313.

RECORDATION DATE: 05/31/2006

REEL/FRAME: 017930/0171
NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
YILMAZ, OSMAN

DOC DATE: 03/31/2006

ASSIGNEE:
WARREN PHARMACEUTICALS, INC.
712 KITCHAWAN ROAD
OSSINING, NEW YORK 10562

SERIAL NUMBER: 60506149
PATENT NUMBER:
FILING DATE: 09/29/2003
ISSUE DATE:
TITLE: TISSUE PROTECTIVE CYTOKINES FOR THE TREATMENT AND PREVENTION OF SEPSIS AND THE FORMATION OF ADHESIONS

SERIAL NUMBER: 10573905
PATENT NUMBER:
FILING DATE:
ISSUE DATE:
TITLE: TISSUE PROTECTIVE CYTOKINES FOR THE TREATMENT OF SEPSIS AND THE

SERIAL NUMBER: 10573905 FILING DATE:
PATENT NUMBER: ISSUE DATE:
PCT NUMBER: US0431789
TITLE: TISSUE PROTECTIVE CYTOKINES FOR THE TREATMENT OF SEPSIS AND THE

ASSIGNMENT SERVICES BRANCH
PUBLIC RECORDS DIVISION

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
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Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

61297 7590 08/21/2009

WARREN PHARMACEUTICALS, INC
712 KITCHAWAN ROAD
OSSINING, NY 10562

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,905	05/30/2006	Michael Brines	WP03-1 A04-US	2092

TITLE OF INVENTION: TISSUE PROTECTIVE CYTOKINES FOR THE TREATMENT AND PREVENTION OF SEPSIS AND THE FORMATION OF ADHESIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	11/23/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
DEBERRY, REGINA M	1647	514-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☒ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 JONES DAY
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

The Kenneth S. Warren Institute, Inc. and Warren Pharmaceuticals, Inc., Ossining, NY

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☑ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 50-3013 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)
☒ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature Eileen E. Falvey
Typed or printed name Eileen E. Falvey
Date 11/20/09
Registration No. 46,097

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APR 2 4 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Brines *et al.*

Confirmation No.: 2092

Serial No.: 10/573,905

Art Unit: 1647

Filed: May 30, 2006

Examiner: DeBerry, Regina M.

For: TISSUE PROTECTIVE CYTOKINES FOR THE TREATMENT AND PREVENTION OF SEPSIS AND THE FORMATION OF ADHESIONS

Attorney Docket No.: WP03-1A04-US

AMENDMENT UNDER 37 C.F.R. § 1.111

Mail Stop Amendment
Commissioner for Patents
PO BOX 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the outstanding non-final Office Action mailed November 24, 2008, and in accordance with 37 C.F.R. §1.111, please consider the amendments and remarks below and enter them into the record for the application. Concurrently submitted herewith is (1) an Amendment Fee Transmittal; (2) a Petition for Extension of Time for two months, from February 24, 2009 up to and including April 24, 2009; and (3) a Credit Card Form authorizing the payment of fees due.

Amendments to the claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin at page 8 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Withdrawn) A method of treating, preventing, delaying the onset of, or reducing sepsis in a mammal comprising administering to the mammal a therapeutically effective amount of at least one chemically modified or mutated erythropoietin and a pharmaceutical carrier.

2.-36. (Canceled)

37. (Withdrawn) The method of claim 1, wherein said sepsis has not proceeded to septic shock.

38. (Withdrawn) A method of enhancing wound healing in a mammal comprising administering to the mammal a therapeutically effective amount of at least one chemically modified or mutated erythropoietin and a pharmaceutical carrier.

39. (Currently Amended) A method of treating, ~~preventing~~, delaying the onset of, or reducing adhesion formation, abnormal fibrous band formation, formation of a connection between organs, or scarring in a mammal comprising administering to the mammal a therapeutically effective amount of at least one erythropoietin that ~~is optionally chemically modified or mutated~~ is chemically modified at one or more lysine residues or the N-terminal amino group, wherein said chemical modification is carbamylation, and a pharmaceutical carrier.

40. (Withdrawn) A method of treating, preventing, delaying the onset of, or reducing a condition associated with elevated IL-6 in a mammal comprising administering a therapeutically effective amount of at least one erythropoietin that is optionally chemically modified or mutated in a pharmaceutical carrier.

41. (Previously Amended) The method of claim 39, wherein said erythropoietin lacks or is diminished for at least one or more of erythropoietin's erythropoietic effects.

42-48. (Canceled)

49. (Withdrawn) A method of treating, preventing, delaying the onset of, or reducing the effects of a condition associated with an effect of proinflammatory cytokines in a mammal comprising administering to the mammal a therapeutically effective amount of at least one chemically modified or mutated erythropoietin, said erythropoietin having at least one polyethylene glycol molecule attached, in a pharmaceutical carrier.

50. (Withdrawn) A method of treating, preventing, delaying the onset of, or reducing the effects of a condition associated with proinflammatory cytokines in a mammal comprising administering to the mammal a therapeutically effective amount of at least one chemically modified or mutated erythropoietin in a pharmaceutical carrier, said erythropoietin having at least one polyethylene glycol molecule attached.

51. (Withdrawn) The method of claim 49 or 50, wherein said erythropoietin is also carbamylated.

52. (Withdrawn) The method of any one of claim 47, wherein said carbamylated erythropoietin is alpha-N-carbamoyl, N-epsilon-carbamoylerythropoietin.

53. (Withdrawn) The method of any one of claim 51, wherein said carbamylated erythropoietin is alpha-N-carbamoyl, N-epsilon-carbamoylerythropoietin

54. (Withdrawn) The method of any one of claim 47, wherein said carbamylated erythropoietin has at least 90% of the lysines carbamylated, 95% of the lysines carbamylated, or 100% of the lysines carbamylated.

55. (Withdrawn) The method of any one of claim 51, wherein said carbamylated erythropoietin has at least 90% of the lysines carbamylated, 95% of the lysines carbamylated, or 100% of the lysines carbamylated.

56. (Currently Amended) The method of any one of claims ~~47~~39, wherein the ~~carbamylated~~ carbamylation of the erythropoietin ~~basis~~ on at least six lysine residues

thereof ~~carbamylated~~, at least seven lysine residues thereof ~~carbamylated~~, or at least eight lysine residues thereof~~carbamylated~~.

57. (Withdrawn) The method of claim 49 or 50, wherein the proinflammatory cytokine comprises at least one of Interleukin or TNF.

58. (Withdrawn) The method of claim 50, wherein the condition associated with proinflammatory cytokines is an ischemia-related condition, allergy, rheumatic disease, or infection.

59. (Withdrawn) A method for treating a condition related to proinflammatory cytokines in a mammal with reduced hematocrit levels comprising administering a therapeutic dose of erythropoietin, said dose sufficient to restore the hematocrit in said mammal, and administering a therapeutic dose of a chemically modified or mutated erythropoietin.

60. (Withdrawn) The method of claim 59, wherein said condition is anemia.

61. (Withdrawn) The method of claim 60, wherein said anemia is associated with cancer or another chronic disease.

62. (Withdrawn) A pharmaceutical composition comprising an amount of at least one chemically modified or mutated erythropoietin effective for use in the method of any one of claims 1, 38 to 40, 49, 50, 58, 59, 60 or 61.

63. (Withdrawn) A pharmaceutical composition comprised of an amount of at least one erythropoietin effective for use in the method of any one of claims 39 to 40.

64. (Withdrawn) The pharmaceutical composition of claim 62, wherein the erythropoietin (i) lacks or is diminished for at least one of erythropoietin's erythropoietic effects; (ii) has at least one polyethylene glycol molecule attached; or (iii) is carbamylated.

65. (Withdrawn) The pharmaceutical composition of claim 62, wherein said erythropoietin is alpha-N-carbamoyl, N-epsilon-carbamoylerythropoietin.

66. (Withdrawn) The method of claim 38, wherein the wound is a result of one or more of trauma, surgery, pressure, burns, diabetes, or vascular insufficiencies.

67. (Previously Presented) The method of claim 39, wherein the adhesion formation is a result of one or more of surgery, trauma, infection, chemotherapy, radiation, or cesarean section.

68. (Withdrawn) A method for testing the ability of a chemically modified or mutated erythropoietin to treat, prevent, delay the onset of, or reduce complications of sepsis, adhesions, or inflammation resulting from infection comprising:

(i) inducing sepsis, adhesions, inflammation, or a combination thereof in a mammal;

(ii) administering to said mammal the erythropoietin to be tested; and

(iii) determining the adhesion score of the mammal,

wherein if the adhesion score determined in step (iii) is less than the adhesion score absent the erythropoietin then said erythropoietin effectively treats, prevents, delays the onset of, or reduces complications of sepsis, adhesions, or inflammation resulting from infection.

69. (Withdrawn) A method for testing the ability of a chemically modified or mutated erythropoietin to treat, prevent, delay the onset of, or reduce complications of sepsis, adhesions, or inflammation resulting from infection comprising:

(i) inducing sepsis, adhesions, inflammation, or a combination thereof in a mammal;

(ii) administering to said mammal the erythropoietin to be tested; and

(iii) determining the illness score of the mammal,

wherein if the illness score determined in step (iii) is less than the illness score absent the erythropoietin, then said erythropoietin effectively treats, prevents, delays the onset of, or reduces complications of sepsis, adhesions, or inflammation resulting from infection.

REMARKS

According to the Office Action mailed November 24, 2008, claims 1, 37-45, and 47-69 are pending in the current application. Claims 1, 37-38, 40, 49-55, 57-66, 68 and 69 have been withdrawn and currently claims 39, 41-45, 47, 48, 56 and 67 are rejected. By this amendment Applicants have: (1) canceled claims 42-45, 47 and 48 without prejudice; (2) amended claim 39 to delete the term "prevent," and the phrase "is optionally chemically modified or mutated;" and (3) amended claim 39 to add "is chemically modified at one or more lysine residues or the N-terminal amino group, wherein said chemical modification is carbamylation," which incorporates the limitations of claims 42 and 47; and (4) amended claim 56 to depend from claim 39 and provide proper antecedent basis for the claim.

Applicants hereby reserve the right to pursue the subject matter of the canceled claims in subsequent filings. These amendments have not added new matter, and Claims 39, 41, 56 and 67 will be pending upon entry of the present amendment.

INFORMATION DISCLOSURE STATEMENT

Applicants acknowledge the Examiner's indication that the various references submitted in Applicant's IDS filed on July 29, 2008 was received and the information contained therein was considered as to the merits. However, although the Office Action, pages 3-4, indicates that the Office Actions and patent interference cited in the IDS were considered, the Examiner has lined through each of these references on the IDS, see pages 4 and 7, indicating that the references have not been considered. Applicants hereby request that the IDS be amended in order to indicate that these submitted references have in fact been considered by the Examiner as the Office Action states.

THE CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ENABLEMENT, SHOULD BE WITHDRAWN

Claims 39, 41-45, 47, 48, 56 and 67 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner maintains that these claims are not enabled for a method of *preventing* adhesion formation, abnormal fibrous band formation, formation of a connection between organs or scarring in a mammal using *an unmodified EPO that is optionally chemically modified or mutated*. Without agreeing to the Examiner's rejection and solely to expedite the prosecution of this application, Applicants have (1) amended claim 39 to delete the term "prevent," and the phrase "is

optionally chemically modified or mutated;" and (2) amended claim 39 to add "is chemically modified at one or more lysine residues or the N-terminal amino group, wherein said chemical modification is carbamylation." These amendments render the current enablement rejection moot as the Examiner, page 4 of the Office Action, indicates that the specification is enabling for the amended scope of claim 39.

Dependent claims 41, 56 and 67 all ultimately depend from claim 39 and incorporate the limitations of claim 39 via their dependencies and therefore are enabled as well. Accordingly, Applicants assert that the specification is enabling for the claimed invention and that the indicated claims should be allowed.

CONCLUSION

Applicants respectfully request consideration and entry of the amendments and remarks into the file for the above-identified application.

Respectfully submitted,

Date: April 24, 2009

Frederick J. Hamble 42,623 (Reg. No.)

WARREN
PHARMACEUTICALS, INC.
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Ossining, New York 10562
(914) 762-7586

Imaged
508991-999041

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

61297 7590 08/21/2009

WARREN PHARMACEUTICALS, INC
712 KITCHAWAN ROAD
OSSINING, NY 10562

10165-042-999

EXAMINER	
DEBERRY, REGINA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/21/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,905	05/30/2006	Michael Brines	WP03-1 A04-US	2092

TITLE OF INVENTION: TISSUE PROTECTIVE CYTOKINES FOR THE TREATMENT AND PREVENTION OF SEPSIS AND THE FORMATION OF ADHESIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	11/23/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Issue & Publication Fee due 11-21-09
Confirm Patent term Adj. / Request to Reconsider Patent Term Adj. due 11-21-09

Notice of Allowability	Application No. 10/573,905	Applicant(s) BRINES ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/24/09.

2. ☒ The allowed claim(s) is/are 39, 41, 56, 67 (renumbered as 1-4, respectively).

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

EXAMINER'S AMENDMENT/COMMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Attorney Michael Yamin on 19 August 2009.

The application has been amended as follows:

Please cancel claims 1, 37, 38, 40, 49-55, 57-66, 68 and 69.

In claim 56, line 1: please change "The method of any one of claims 39" to Tthe method of claim 39".

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

/R. M. D./
Examiner, Art Unit 1647
8/19/09